Abu	0	0.5
Asp	0.4	1.0

SUPPORT FOR THE AMENDMENTS

The specification and Claim 1 have been amended to recite that the weight percentages are based on the total weight of the amino acids. This is supported by the specification at pages 6-8. As is clear from that description, the amino acid composition is prepared by combining the amino acids and then added to a dialyzer fluid. Therefore, as one skilled in the art would readily appreciate, the weight percentages of the amino acids in the composition are based on the total weight of the amino acids. Newly added Claim 20 is supported by the specification at pages 3-15 and by original Claims 1-19.

The specification has also been amended to replace the Abstract.

No new matter is believed to have been added to this application by these amendments.

REMARKS

Claims 1-23 are active in this application. Claims 1-8 are under active examination. Favorable reconsideration is respectfully requested.

The present invention relates to an amino acid composition suitable for hemodialysis, comprising amino acids in the following proportions, based on the total weight of the amino acids:

	wt%	wt%
	Lower Limit	Upper Limit
Gln	14.0	23.0

Ala	7.0	12.0
Pro	6.0	10.5
Val	5.0	9.5
Gly	3.5	6.0
Lys	6.5	11.0
Leu	3.5	6.0
Thr	3.0	5.5
Ser	2.0	4.0
Arg	40.	6.5
His	2.5	5.0
Ile	1.5	3.0
Tyr	2.0	3.8
Orn	2.2	4.5
Glu	1.5	3.5
Phe	2.0	3.5
Cys	1.8	3.5
Asn	1.1	2.2
Trp	1.3	2.8
Cit	1.0	2.0
Met	0.5	1.2
Abu	0	0.5
Asp	0.4	1.0

See Claim 1.

It is important to note that the claimed composition contains Gln, Tyr, Cys, Asn, and Cit.

The rejection of Claims 1-4 under 35 U.S.C. §103(a) based on Quarto di Palo et al. is respectfully traversed. This reference fails to suggest the claimed amino acid composition suitable for hemodialysis.

Quarto di Palo et al. describe a dialysis solution containing amino acids based on the concentration of normal (i.e., healthy) plasma. See page 112, column 2, second paragraph. The Table at page 113 of the reference presents a summary of the amino acid content of normal plasma and the dialysis bath described in the reference. For convenience, the Table is reproduced below.

AMINO ACID CONTENT IN NORMAL PLASMA AND DIALYSIS BATH (in μM/l)

Amino acids	Plasma	Dialysis bath
Aspartic acid	0 - 15.7	3.0
Threonine	79.7 - 163.7	121.7
Serine	51.4 - 154.1	106.5
Glutamic acid	6.9 - 75	52.4
Proline	88.6 - 352.7	230.2
Glycine	78.6 - 238.44	203.8
Alanine	228.1 - 520.2	377.5
Citrulline	15.5 - 63.9	—
Valine	146.0 - 337	257
Cystine	15 - 80	—
Methionine	12.1 - 31	24.8
Isoleucine	32.8 - 91	76.3
Leucine	76.5 - 180	141.1
Tyrosine	37.5 - 88.4	—
Phenylalanine	31.5 - 77.5	49.5
Tryptophan	34.5 - 72	27
Ornithine	47 - 73	60
Lysine	123.5 - 213	186.2
Histidine	51.5 - 141.8	74
Arginine	30 - 119	90.1

Referring to the Table above, the dialysis solution described by Quarto di Palo et al. does not contain the following amino acids: Gln, Tyr, Cys, Asn, and Cit. Nor is there any discussion of these amino acids in the reference.

In contrast, the claimed amino acid composition contains Gln, Tyr, Cys, Asn, and Cit.

In the Official Action dated June 28, 2002, the Office states at page 5:

> Claims 1-8 essentially differ from the dialyzer fluid comprising the claimed amino acid concentrations in its claimed proportions.

This is not the case at all. The dialyzer fluid described in the reference is missing five of the amino acid components of the claimed composition, i.e., Gln, Tyr, Cys, Asn, and Cit. There is simply nothing in Quarto di Palo et al. which would suggest adding these amino acids to the dialyzer fluid described therein.

The Office appears to be using Table 2 at page 6 of the present specification, which lists the amino acid concentrations in the plasma of a healthy person, in support of the rejection. One would not be motivated to modify the fluid described by Quarto di Palo et al. in view of the Table to arrive at the claimed amino acid composition. Quarto di Palo et al. explicitly state that the composition described in this reference is based on normal plasma, i.e., that of a healthy person. Yet, the fluid described in the reference lacks the amino acids Gln, Tyr, Cys, Asn, and Cit, even though Table 2 at page 6 of the specification indicates that those amino acids are present in healthy plasma.

Based on the foregoing, the claimed amino acid composition is not suggested by Quarto di Palo et al. alone or in combination with information described in Table 2 at page 6 of the present application. Accordingly, Claim 1 and claims dependent thereon are not obvious over Quarto di Palo et al. Withdrawal of this ground of rejection is respectfully requested.

The rejections of the claims under 35 U.S.C. §112, first and second paragraphs, are believed to be obviated by the amendment submitted above. Claim 1 as amended specifies that the weight percentages specified therein are based on the total weight of the amino acids. Accordingly, withdrawal of these grounds of rejection is respectfully requested.

Regarding the Restriction Requirement, Applicants confirm the election of Group I, Claims 1-8. Since these claims are allowable for the reasons set forth above, Applicants request that non-elected method Claims 9-12 be rejoined with Claims 1-8.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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IN THE CLAIMS

Please amend the claims as follows.

--1. (Amended) An amino acid composition suitable for hemodialysis, comprising amino acids in the following proportions, based on the total weight of the amino acids:

	wt% Lower Limit	wt% Upper Limit
Gln	14.0	23.0
Ala	7.0	12.0
Pro	6.0	10.5
Val	5.0	9.5
Gly	3.5	6.0
Lys	6.5	11.0
Leu	3.5	6.0
Thr	3.0	5.5
Ser	2.0	4.0
Arg	4.0	6.5
His	2.5	5.0
Ile	1.5	3.0
Tyr	2.0	3.8
Orn	2.2	4.5
Glu	1.5	3.5
Phe	2.0	3.5
Cys	1.8	3.5

Asn	1.1	2.2
Trp	1.3	2.8
Cit	1.0	2.0
Met	0.5	1.2
Abu	0	0.5
Asp	0.4	1.0

ABSTRACT

The invention relates to a special amino acid mixture for hemodialysis as well as to the dialysis solution that can be prepared from the amino acid mixture. When the amino acid mixtures according to the invention are used for such purposes, the "shrinking men" phenomenon can be prevented. The present invention also relates to a hemodialysis process and apparatus. This aspect of the invention provides a closed dialysis system with a dialyzer solution containing the amino acid mixtures according to the invention.